

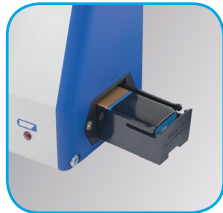
Reference Guide

Correct Usage of EASYSpray and DUPLOSPRAY Pressure Regulator



EASYSpray and DUPLOSPRAY I

EASYSpray Pressure Regulator Operation (open surgery)



- 1 Insert 9V battery into the EASYSpray Pressure Regulator device



- 4 Connect Spray Set filters to EASYSpray device. Connect the blue filter to the blue female luer connector and the clear filter to the male luer connector



- 2 Connect EASYSpray device to IV pole or cart rail using the clamps on the back of the device



- 5 Turn the on/off switch on the front side of the EASYSpray to the ON (I) position



- 3 Use suitable connection tube to connect the EASYSpray device to medical air (ranging 3.5 – 7 bar / 50 – 100 psi)

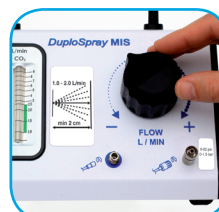


- 6 Check the gauge on the EASYSpray device for the appropriate pressure range of 1.5-2.0 bars (21.5-28.5 psi). Adjust pressure setting by turning the black pressure control knob

DUPLOSPRAY MIS Pressure Regulator Operation (laparoscopic procedures)



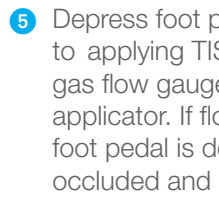
- 1 Position DUPLOSPRAY System so the foot pedal is placed next to the surgeon's foot at time of application



- 4 While depressing foot pedal, adjust gas flow rate to 1.0-2.0 liters per minute. Check gas flow by noting height of ball in flow gauge while stepping on foot pedal



- 2 Attach gas supply hose, located at back of regulator, to source of medical grade CO₂



- 5 Depress foot pedal to start gas flow prior to applying TISSEEL Fibrin Sealant. Check gas flow gauge on regulator before inserting applicator. If flow level ball does not move when foot pedal is depressed, the applicator tip is occluded and should be replaced



- 3 Attach spray set to regulator. Connect the blue vent line filter to the blue female luer and the clear gas line filter to the male luer on the regulator

MIS Pressure Regulator - Instructions for correct usage

CAUTION BOX

Any application of pressurised gas may be associated with a potential risk of air or gas embolism, tissue rupture or air or gas entrapment with compression, which may be life threatening if the product is sprayed incorrectly

Precautions

For TISSEEL Fibrin Sealant and ARTISS Solutions for Sealant

- In open-wound surgery: when applying sprayable fibrin solutions for sealant using a pressure regulator device, the maximum pressure should be 2.0 bar (28.5 psi). The product should be sprayed at a distance at least 10 cm from the tissue surface.
- Spray application should only be used if it is possible to accurately judge the spray distance as recommended by the manufacturer. Do not spray closer than the recommended distances.
- Prior to applying sprayable fibrin solutions for sealant, the surface area of the wound should only be dried using standard techniques (eg, intermittent application of compresses, swabs, use of suction devices).
- Blood pressure, pulse rate, oxygen saturation and end tidal CO₂ should be monitored closely when spraying fibrin solutions for sealant using a pressure regulator device, because of the possibility of occurrence of air or gas embolism.
- Regulators should be used in line with manufacturer recommendations and the SmPC and Instruction for Use.

For TISSEEL Fibrin Sealant only

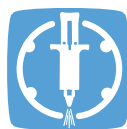
- In laparoscopic procedures: Use CO₂ only when using spray application. When applying the product as a spray using a CO₂ pressure regulator device, the maximum pressure should be 1.5 bar (22 psi). The product should be sprayed at a distance at least 2cm (recommended range 2-5cm) from the tissue surface.

For ARTISS Solutions for Sealant only

- ARTISS is recommended for subcutaneous use only. ARTISS is not recommended for laparoscopic use.



TISSEEL
[Fibrin Sealant]



ARTISS
[Solutions for Sealant]

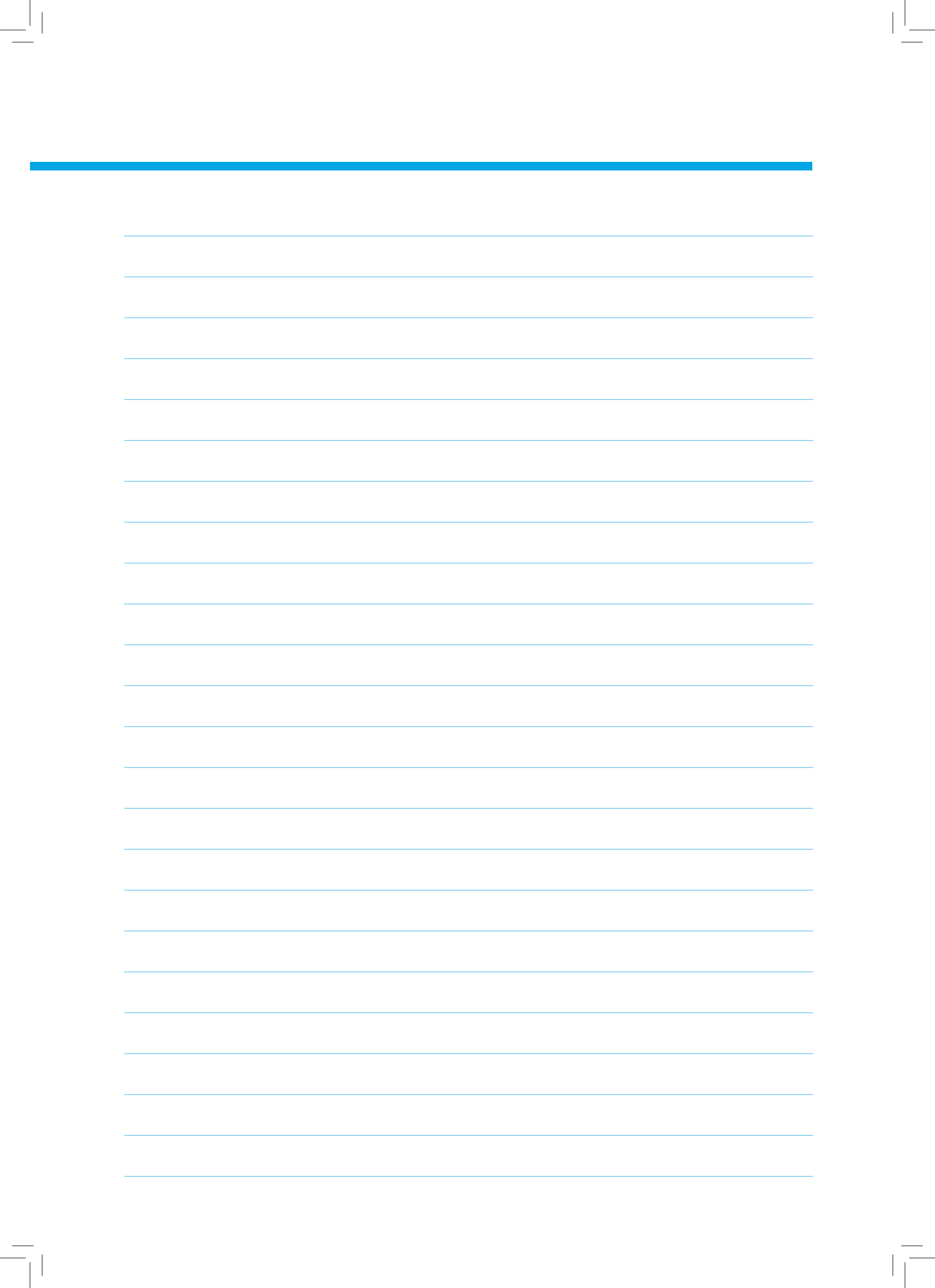
Fibrin Sealant	Surgery	Spray set to be used	Applicator tips to be used
TISSEEL	Open surgery	TISSEEL/ARTISS Spray Set	n.a.
		TISSEEL/ARTISS Spray Set 10 Pack	n.a.
	Laparoscopic/ minimally invasive procedures	n.a.	DUPLOSPRAY MIS Applicator 20cm
			DUPLOSPRAY MIS Applicator 30cm
			DUPLOSPRAY MIS Applicator 40cm
			Replaceable Tip
ARTISS	Open surgery	TISSEEL/ARTISS Spray Set	n.a.
		TISSEEL/ARTISS Spray Set 10 Pack	n.a.
	Laparoscopic/ minimally invasive procedures	n.a	n.a

CAUTION: Any application of pressurised gas may be associated with a potential risk of air or gas embolism, tissue necrosis and other complications. Please refer to the product literature for appropriate measures to address these risks by observing the recommended minimum spraying distance and the maximum spraying time.

Recommended Pressure and Distance | Overview

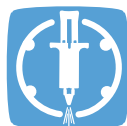
	Pressure regulator to be used	Recommended distance from target tissue	Recommended spray pressure/flow rate
	EASYSPRAY	10-15cm	1.5-2.0 bar (21.5-28.5 psi).
	EASYSPRAY		
	DUPLOSPRAY MIS Regulator	2-5 cm	1.0-2.0 L/min (1.2-1.5 bar/ 18-22 psi)
	DUPLOSPRAY MIS Regulator NIST B11		
	DUPLOSPRAY MIS Regulator		
	DUPLOSPRAY MIS Regulator NIST B11		
	DUPLOSPRAY MIS Regulator		
	DUPLOSPRAY MIS Regulator NIST B11		
	DUPLOSPRAY MIS Regulator		
	DUPLOSPRAY MIS Regulator NIST B11		
	DUPLOSPRAY MIS Regulator		
	DUPLOSPRAY MIS Regulator NIST B11		
	EASYSPRAY	10-15cm	1.5-2.0 bar (21.5-28.5 psi)
	EASYSPRAY		
	n.a	n.a	n.a

tissue rupture or air or gas entrapment with compression, which may be life threatening. Be sure to take the maximum pressure provided in the appropriate spray set instructions for use and in the table above.





TISSEEL
[Fibrin Sealant]



ARTISS
[Solutions for Sealant]

Baxter

Baxter Healthcare Ltd
Wallingford Road, Compton
Newbury, RG20 7QW

Surecall Tel: +44 (0) 1635 206345
Surecall Fax: +44 (0) 1635 206071
Email: surecall@baxter.com

For detailed information please contact your local representative.

Baxter, Tisseel, Tissucol, Artiss, Duplospray, and Easyspray are trademarks of
Baxter International Inc., its subsidiaries or affiliates

UK/MG24/13-0003 September 2013